

**REPORT BY THE
AUDITOR GENERAL
OF CALIFORNIA**

**HOW MEDI-CAL AND OTHER HEALTH CARE PROVIDERS
MANAGE THEIR PHARMACEUTICAL EXPENDITURES**

**How Medi-Cal and Other Health Care Providers
Manage Their Pharmaceutical Expenditures**

P-062, August 1991

**Office of the Auditor General
California**



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P-062

Honorable Robert J. Campbell, Chairman
Members, Joint Legislative Audit Committee
State Capitol, Room 2163
Sacramento, California 95814

Dear Mr. Chairman and Members:

The Office of the Auditor General presents its report concerning the drug benefit portion of the Medi-Cal program. The report compares strategies that Medi-Cal uses to manage the cost of the drug benefit portion of Medi-Cal to strategies that various private and public health care providers use in their health care programs.

We conducted this audit to comply with Chapter 1643, Statutes of 1990.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kurt Sjoberg".

KURT R. SJÖBERG
Auditor General (acting)

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Summary

Results in Brief

Chapter 1643 of the Statutes of 1990 requires the Office of the Auditor General to conduct a study of the drug contracting program of the California Medical Assistance Program (Medi-Cal). We conducted this study to compare Medi-Cal's strategies with the strategies various private and public health care providers use to manage the cost of the drug benefit portions of their health care programs. Based on our surveys of Medi-Cal prescribing physicians, 12 major pharmaceutical purchasers, interviews of officials of the Medi-Cal program, and our review of numerous studies on the subject of the rising cost of pharmaceuticals, we can make the following observations:

- Medi-Cal drug expenditures grew from \$231 million in 1984 to an estimated \$516 million in 1989, or by 124 percent. This growth in expenditures is due to both an expanded use of the Medi-Cal drug benefit and also an increase in the average cost per prescription.
- Twelve major pharmaceutical purchasers we surveyed employ a wide variety of strategies designed to control their expenditures for pharmaceuticals. These controls fall into two broad categories--utilization and price. Utilization controls monitor or restrict the amounts and types of drugs for which the pharmaceutical purchaser pays whereas price controls contain pharmaceutical costs by limiting the price that purchasers pay for drugs.

- In an attempt to stem increases in Medi-Cal expenditures, Medi-Cal also uses most of the same utilization and price strategies as those identified by the major pharmaceutical purchasers we surveyed.
- In July 1990, legislation was passed that established a drug discount program designed to reduce the prices that Medi-Cal pays for drugs.
- For a sample of six prescription drugs, we surveyed six pharmacists on what amounts they would bill Medi-Cal and we determined what amounts they would be reimbursed. We found that for the same prescription drug, a significant difference exists in the amounts pharmacies would have billed Medi-Cal and the amounts Medi-Cal would have reimbursed the six pharmacies.
- The variation in amounts of reimbursements among the six pharmacies revealed that a significant difference exists in what Medi-Cal would have reimbursed the six pharmacies for the same drug.

Background Medi-Cal is an \$8.7 billion program funded jointly by the state and federal governments and administered by the California Department of Health Services (department). Medi-Cal provides health care services to low-income persons and families, the medically needy, and public assistance recipients. Medi-Cal beneficiaries are entitled to a variety of medically necessary services including physician care, hospital care, psychological counseling, and prescription drugs.

**Strategies
To Control
Expenditures**

The 12 major pharmaceutical purchasers we surveyed, which included government entities, hospitals, hospital buying groups, and health maintenance organizations, use a wide variety of techniques to control pharmaceutical costs. These techniques

fall into either one of the two categories of utilization and price control.

Utilization controls include drug formularies, which are lists of drugs and dosages that a major pharmaceutical purchaser believes to be the most useful and cost-effective; generic substitution which is the substitution of chemically identical but less expensive generic drugs instead of more expensive brand name drugs; therapeutic substitution which is the substitution of chemically different but therapeutically equivalent drugs; drug education programs to change or influence physicians' prescribing habits; drug utilization reviews to identify physicians who prescribe drugs inappropriately; dispensing controls at the pharmacy level to limit the quantity dispensed and to ensure beneficiary eligibility; and beneficiary copayments to discourage beneficiaries from purchasing unnecessary drugs.

Price controls include limits on the amounts major pharmaceutical purchasers will reimburse a pharmacy for filling prescriptions, and price discounts that purchasers negotiate directly with pharmaceutical manufacturers.

The pharmaceutical purchasers we surveyed use the techniques discussed above in a variety of combinations to control drug costs. Major pharmaceutical purchasers such as government entities and buying groups, which are less active in applying drug utilization controls, focus their efforts on price control, using volume purchasing as a tool to negotiate manufacturer price discounts. These organizations also negotiate price discounts by entering "bundling" agreements, agreeing to purchase multiple-source drugs from a particular vendor in exchange for a price discount on that vendor's single-source drugs. (Drug vendors consist of manufacturers and wholesalers.) Hospitals and health maintenance organizations use both utilization and price controls to contain drug costs.

**Attempts
To Control
Medi-Cal
Drug Costs**

Medi-Cal uses many of the same utilization controls to contain pharmaceutical costs as the drug purchasers we surveyed, but until recently, Medi-Cal's price control efforts focused exclusively on pharmacy reimbursement limits. However, in July 1990, the department established a drug discount program to negotiate with drug manufacturers for price discounts. The department estimated that the drug discount program will save the state and federal governments \$3.3 million in fiscal year 1990-91. However, this estimate does not take into account a budgeted \$659,000 cost to the State associated with operating the program.

In addition to obtaining discounted prices for pharmaceuticals, the drug discount program is also designed to simplify the addition of new drugs to Medi-Cal's list of contract drugs (which has now replaced the formulary). Before implementing the program, the department could add new drugs to the formulary only through a regulation process, which, for two drugs that we researched, took approximately 15 months. Under the drug discount program, the department can add new single-source drugs to the list of contract drugs whenever the department and a manufacturer negotiate a rebate contract. For two drugs that we researched, adding these drugs through the negotiation process took approximately four months for one drug and seven months for the other.

**Agency
Comments**

The Department of Health Services believes our report contains a fair and reasonable assessment of how third parties, including Medi-Cal, control pharmaceutical expenses while maintaining access to needed drug products.

Introduction

Chapter 1643 of the Statutes of 1990 requires the Office of the Auditor General to conduct a study of the drug benefit portion of the California Medical Assistance Program (Medi-Cal). We conducted this study to compare Medi-Cal's strategies with the strategies various private and public health care providers used to manage the cost of the drug benefit portions of their health care programs.

Medi-Cal and Prescription Drug Costs

The federal Health Care Financing Administration (HCFA) oversees the Medicaid program, which, together with state governments, provides basic health services, including prescription drugs, to public assistance recipients, low-income individuals and families, and medically needy individuals. Through Medicaid, the federal government provides matching funds to states that have instituted medical care programs, such as Medi-Cal. Medi-Cal is an \$8.7 billion program funded jointly by the state and federal government and administered by the California Department of Health Services (department). Authorized by Title XIX of the federal Social Security Act and Section 14000 et seq. of the state Welfare and Institutions Code, Medi-Cal provides health care services to public assistance recipients, low-income individuals and families, and the medically needy. During fiscal year 1990-91, an average of four million persons qualified for Medi-Cal services each month. Under the program, Medi-Cal beneficiaries are entitled to a variety of medically necessary services, including physician care, hospital care, psychological counseling, and prescription drugs.

In recent years, prescription drug expenditures for Medi-Cal beneficiaries have continued to increase. According to a 1990 study prepared by SysteMetrics/McGraw-Hill, Inc., Medi-Cal drug expenditures grew from \$231 million in 1984 to an estimated \$516 million in 1989, or by 124 percent. This means that Medi-Cal's drug expenditures grew by a compounded rate of 17 percent during each year between 1984 and 1989.

This growth in drug expenditures is not unique to California. In a June 1991 study completed for our office, Price Waterhouse reported that national expenditures for drugs and other medical items grew from \$20.1 billion in 1980 to \$41.9 billion in 1988. This represents an increase of 108.5 percent, or a compounded annual rate of growth of 9.6 percent between 1980 and 1988. In a January 1991 study prepared for the Michigan Pharmacists Association, Public Sector Consultants, Inc., reported that Michigan's prescription drug costs for Medicaid recipients grew from \$71.6 million in fiscal year 1982 to \$156.6 million in fiscal year 1989. This represents an increase of 119 percent, or a compounded annual rate of growth of 11.8 percent between fiscal year 1982 and fiscal year 1989.

The SysteMetrics/McGraw-Hill study attributes the growth in Medi-Cal drug expenditures to both an increase in average cost per prescription and the expanded use of the Medi-Cal drug benefit program. This rise in average cost per prescription accounted for 39 percent of the increase in Medi-Cal expenditures between 1984 and 1989. Growth in the number of Medi-Cal beneficiaries receiving prescription drugs and in the number of prescription drugs used by each Medi-Cal patient accounts for 61 percent of the growth in Medi-Cal drug expenditures.

This report will focus on current efforts by Medi-Cal and other health care providers to stem the increases in the prices they pay for pharmaceuticals. Also, the report will detail various strategies that Medi-Cal and the other health care providers use to ensure that the drug benefit portions of their health care programs are used only when necessary.

**Pharmaceutical
Distribution
System**

According to a report prepared for the HCFA, the system of distribution of pharmaceuticals in the United States involves more than 750 U.S. drug manufacturers or pharmaceutical companies, more than 86 drug wholesalers, and about 55,000 pharmacies. The manufacturers that do not distribute their own product rely on the 86 wholesalers that operate the nearly 300 wholesale distribution centers in the United States. For the individual pharmacy, the wholesaler reduces the number of transactions necessary for purchasing a full line of drug products. Without the wholesaler, an individual pharmacy would have to purchase from several hundred manufacturers weekly or monthly. In most metropolitan areas, wholesalers can deliver drugs with same-day service, and nearly all communities have access to next-day service. Medi-Cal beneficiaries rely on community pharmacies throughout the State to fill their prescriptions.

**Scope and
Methodology**

Chapter 1643 of the Statutes of 1990 requires our office to collect information on how various private and public health care providers, including the department, are managing the price of drugs associated with the drug benefit portion of their health care programs. The statutes specifically direct that we determine how various health care providers secure reasonable or lowest prices on the single- and multiple-source drugs they buy. A single-source drug is a drug that is marketed by only one manufacturer or distributor. A multiple-source drug is a drug that is marketed by two or more manufacturers or distributors or by both.

We are also required to determine what types of dispensing fees these health care providers have in place, whether these health care providers have established copayments, and how such requirements affect beneficiaries and providers. Further, we are required to determine how open and restricted formularies and the list of contract drugs affect the cost of a health care program and beneficiaries' access to drugs. An open formulary is a compilation of all drug products that are available for use in a target patient population. A restricted formulary restricts the

list of drug products. Drugs may be left off a formulary because of one or more of the following: they are considered less than effective; they are available over the counter; they are used for cosmetic purposes and are not considered essential to the patient's health; they are subject to patient misuse and abuse; or the program does not wish to cover them for administrative, cost, or other reasons. Medi-Cal's formulary contained more than 500 drugs and identified drugs that could be provided to Medi-Cal beneficiaries without receiving prior authorization from the department. In July 1990, the Medi-Cal formulary became the list of contract drugs.

In addition, the statutes require that we determine whether federal reimbursement limits influence the inclusion of certain drugs on the Medi-Cal list of contract drugs or influence Medi-Cal beneficiaries' access to those drugs. The list of contract drugs includes all drugs previously listed on the Medi-Cal formulary except for those drugs deleted as a result of contract negotiations between the department and manufacturers or for those drugs the department suspends from the list.

We were also required to determine whether different pharmacies charge the Medi-Cal program different amounts for the same drugs. Further, we were required to determine the percent of the national market that Medi-Cal represents for single-source breakthrough drugs and to collect information on the pharmaceutical manufacturers' costs associated with the research, development, production, and marketing of single- and multiple-source drugs. We defined breakthrough drugs as those drugs classified by the Food and Drug Administration (FDA) as either a new molecular entity offering significant therapeutic gain (known as a "1A" drug) or a high-priority AIDS drug (known as a "1AA" drug).

To identify strategies various major pharmaceutical purchasers use to manage the pharmaceutical cost portions of their health care programs, we surveyed, either by phone or in person, officials of the department's Medi-Cal pharmaceutical program, the California Department of General Services, Los Angeles County, the United States Department of Veterans Affairs, two Canadian

government entities, four hospitals or hospital buying groups (hospitals that associate to purchase pharmaceuticals as a group), and five health maintenance organizations. Throughout this report, we refer to these various organizations as "major pharmaceutical purchasers." (We present the information we obtained on the actions of two Canadian government entities to regulate the price of pharmaceuticals in Appendix A.) We also reviewed, when possible, these organizations' formularies; their descriptions of drug plan benefits, policies, and procedures; and their annual reports. In addition, we reviewed research reported in various health care journals and studies provided by professional organizations within the health care industry.

We contracted with a pharmaceutical economist to determine the effect of open and restricted formularies on program costs. (We present his work on this issue in Appendix B.) In addition, to assess the effect of formularies and prior authorization requirements on Medi-Cal beneficiaries' access to drugs, we surveyed more than 400 physicians who served Medi-Cal patients in fiscal year 1989-90 concerning the physicians' willingness to prescribe drugs not included on Medi-Cal's list of contract drugs. (We present these issues in Appendix C.)

To determine the effect of federal reimbursement limits on the department's inclusion of certain drugs on Medi-Cal's list of contract drugs and on Medi-Cal beneficiaries' access to drugs, we interviewed department officials who are involved in adding drugs to the list of contract drugs. (We discuss the effect of federal reimbursement limits on Medi-Cal's list of contract drugs and on beneficiaries' access to drugs in Appendix C.) In addition to reviewing the effect of federal reimbursement limits, we surveyed six pharmacists concerning the prices they charge for a sample of six multiple-source drugs. We compared the amounts that each pharmacy would have charged to Medi-Cal with state and federal reimbursement limits.

We attempted to determine Medi-Cal's percentage of the national market for single-source breakthrough drugs. The expenditure data that we reviewed were limited to expenditures

for retail pharmacies and do not reflect Medi-Cal or national expenditures for drugs administered in hospital settings. We were able to obtain both Medi-Cal and national expenditure data on only 2 of the 15 breakthrough drugs approved by the FDA from 1988 through 1990. For one of the drugs, Ifex, which is used to treat cancer, Medi-Cal spent less than one hundredth of one percent of national expenditures in 1990. For the other drug, Diflucan, used to treat AIDS, Medi-Cal spent \$624,000 in calendar year 1990, which represents 3.9 percent of national expenditures for the drug.

To determine pharmaceutical manufacturers' costs for research, development, manufacturing, and marketing, we reviewed the 1990 annual reports for four companies whose pharmaceutical sales represented at least 70 percent of their net sales. We also reviewed the annual reports of three additional companies that reported pharmaceutical research and development costs separately from costs for the remainder of their business. (We present this information in Appendix D.)

Finally, in Appendix E, we present statistics concerning the pharmaceutical management practices of a large sample of health maintenance organizations throughout the United States.

Chapter 1 Strategies Used by Twelve Major Pharmaceutical Purchasers To Control Pharmaceutical Expenditures

Chapter Summary

Our review of relevant literature and our survey of major pharmaceutical purchasers other than the California Medical Assistance Program (Medi-Cal) revealed a variety of strategies that major pharmaceutical purchasers may employ to control the increase in their expenditures on pharmaceuticals. The strategies, or controls, fall into two broad categories--utilization and price. Utilization controls monitor or restrict the amounts and types of drugs for which the major pharmaceutical purchaser pays whereas price controls contain pharmaceutical costs by limiting the price that purchasers pay for drugs. This chapter discusses the utilization and price strategies available for controlling pharmaceutical expenditures and how the 12 major pharmaceutical purchasers we surveyed are applying those controls.

Utilization and Price Controls

In its January 1990 report--Skyrocketing Prescription Drug Prices: Turning a Bad Deal Into a Fair Deal--the United States Senate Special Committee on Aging surveyed pharmacy directors at 63 U.S. hospitals, 50 state Medicaid programs, 12 major health maintenance organizations, and 4 large hospital and nursing home prescription drug buying groups. The report concluded that federal and state governments pay higher prescription drug prices through their Medicaid programs than any other major purchasers of prescription drugs. In its August 1989 report--Prescription Drug Prices: Are We Getting Our Money's Worth?--the committee reported that some organizations, such as the Department of Veterans Affairs, hospitals, and health maintenance organizations are negotiating prices directly with pharmaceutical manufacturers at discounts of 41 to 99 percent off the published average wholesale price.

To determine how organizations other than Medi-Cal negotiate favorable pharmaceutical prices and what methods they use to control the utilization and cost of prescription drug benefits, we surveyed various entities. These entities are three government organizations, the United States Department of Veterans Affairs, the County of Los Angeles, and the California Department of General Services; four hospitals or hospital buying groups that purchase pharmaceuticals for hospitals; and five health maintenance organizations that either purchase pharmaceuticals or pay for pharmaceuticals that intermediaries, such as pharmacies, purchase and provide to the organizations' members or beneficiaries. In this chapter we refer to all of the organizations as major pharmaceutical purchasers.

Methods for controlling pharmaceutical costs fall into two main categories: utilization controls and price controls. Utilization controls monitor or restrict the amounts and types of prescription drugs for which the major pharmaceutical purchaser will pay. Utilization controls include drug formularies, generic substitution, therapeutic substitution, prescriber education programs, drug utilization reviews, dispensing controls, and beneficiary copayments. Price controls contain prescription drug costs by limiting the price that major pharmaceutical purchasers pay for pharmaceuticals. These controls include pharmacy reimbursement limits and negotiated price discounts.

Drug Formularies

A drug formulary is a list of drugs and dosages that a major pharmaceutical purchaser believes to be the most useful and cost-effective for patient care. Formularies are usually established by pharmacy and therapeutics committees that may comprise physicians, pharmacists, other health care professionals, and administrators.

In deciding whether to include a drug on the formulary, a pharmacy and therapeutics committee may consider factors such as the drug's effectiveness, side effects, ease of administration, and cost and the availability of other drugs to treat the same

condition. The committee may also identify certain drugs or classes of drugs that the major pharmaceutical purchaser will not cover under any circumstances. Commonly excluded items include over-the-counter drugs, drugs used for cosmetic purposes, and drugs prescribed for uses other than those approved by the United States Food and Drug Administration.

Formularies may vary in their restrictiveness. One type of formulary is merely a guideline for physicians to use when prescribing drugs, and physicians are free to prescribe non-formulary drugs for beneficiaries without restriction. Other formularies may require physicians to consult with the pharmacy and therapeutics committee or a clinical pharmacist and obtain authorization to prescribe a non-formulary drug.

Generic Substitution

Generic or multiple-source drugs are prescription drugs that are not covered by a patent and are available from multiple vendors. The National Pharmaceutical Council defines generic substitution as “the act of dispensing a different brand or an unbranded drug product for the drug product prescribed (i.e., chemically the exact same drug in the same dosage form, but distributed by different companies).” Major pharmaceutical purchasers may require pharmacists to substitute a brand name product with a less expensive identical product whenever such a product is available when a physician writes a prescription for the brand name product. Physicians may override automatic generic substitution by indicating on the prescription that generic substitution is not permitted or that the brand name drug is medically necessary. Some major pharmaceutical purchasers allow beneficiaries to request a brand name drug instead of a generic but require the beneficiary to pay additional charges to receive the brand name drug.

Therapeutic Substitution

Therapeutic substitution, usually used to save money, is the replacement of one drug with a chemically different but therapeutically equivalent drug. Pharmacy and therapeutics committees may prepare a list of therapeutically equivalent drugs that pharmacists may substitute without consulting the prescribing physician. Alternatively, pharmacists may contact physicians directly to request approval before making a therapeutic substitution. Substitution is allowed only in cases in which the substituted drug will result in the same therapeutic benefit for the patient. Therapeutic substitution may allow a major pharmaceutical purchaser to ensure use of the least expensive of the equivalent drugs. According to one of the major pharmaceutical purchasers we surveyed, such substitution can also increase the purchase volume of the preferred substitute. This increased purchase volume may allow the major pharmaceutical purchaser to negotiate an even more favorable price with the manufacturer. By using only one drug among several therapeutic equivalents, major pharmaceutical purchasers may encourage price competition among the manufacturers of the equivalent drugs.

“H2 antagonists” are one example of a therapeutic class of prescription drugs that contains several chemically different drugs of varying prices, all of which physicians prescribe to treat ulcers. A physician might prescribe one particular H2 antagonist for a patient, and the pharmacist could dispense another, less expensive one after either consulting an approved list of therapeutic equivalents for the prescribed drug or consulting directly with the prescribing physician. Other therapeutic classes that contain several chemically different but therapeutically equivalent drugs are blood pressure medications, antibiotics, and non-steroidal anti-inflammatory drugs.

Prescriber Education Programs

Major pharmaceutical purchasers may attempt to change or influence the prescribing habits of physicians by offering prescriber education programs. These programs take many forms. Some use

periodic newsletters containing information on prescription drug costs and the availability of new generic drugs while others use a combination of printed information and personal contacts between physicians and clinical pharmacists. For example, one of the purchasers we surveyed stated that therapeutic classes containing numerous drugs of varying cost for treating the same condition have been the focus of recent educational campaigns. The campaigns attempt to raise physicians' awareness of when they can and should prescribe the least costly drug therapy and when they may need to prescribe one of the more costly alternatives. In at least one prescriber education program, the major pharmaceutical purchaser severely restricts contact between physicians and representatives of prescription drug manufacturers so that the physicians will not be subject to the representatives' sales presentations for non-formulary drugs or drugs that are not cost-effective.

Research has shown that educating physicians about drug utilization can be a cost-effective method of reducing Medicaid drug expenditures. In their 1986 article "Economic and Policy Analysis of University-based Drug 'Detailing,'" Soumerai and Avorn reported the results of a controlled test involving 435 office-based physicians in three states and the District of Columbia. The authors found that physician education resulted in a 13 percent cost savings to Medicaid in the nine months following the test in comparison with a control group that did not receive such education. In the test, physician education consisted of printed information accompanied by face-to-face interactions between clinical pharmacists and physicians. Such education was designed to reduce the number of prescriptions for three drugs for which safer or more cost-effective therapies were available. Soumerai and Avorn then estimated the costs and benefits of providing the same educational program to 10,000 physicians over six months. Based on the results of their controlled test, they estimated that the expanded program would result in a net benefit to Medicaid of \$111,000 per 1,000 physicians over six months, assuming no substitution of over-the-counter drugs for the three drugs, and \$66,000 per 1,000 physicians, assuming a large substitution of over-the-counter drugs for the three drugs.

Drug Utilization Review

Drug utilization review is a process by which major pharmaceutical purchasers monitor the number and types of prescriptions physicians write for beneficiaries or members to determine if physicians or groups of physicians are prescribing drugs in a manner that is fiscally or therapeutically inappropriate. Review programs may examine the number or cost of prescriptions per member or beneficiary per month and physicians' compliance with the formulary. At least one of the major pharmaceutical purchasers we surveyed supplies reports to physicians comparing the prescribing practices and formulary compliance of individual physicians or groups of physicians with those of other physicians in the same specialty or in similar groups. These reports may also identify for individual physicians those patients for whom the physician prescribed a non-formulary drug and suggest alternative drugs on the formulary that the physician could have prescribed. The same major pharmaceutical purchaser uses average drug costs for physician groups to determine the amount of a year-end financial incentive to pay to those groups closely complying with the purchaser's formulary.

In their 1990 article "Prescription Drugs, Practicing Physicians, and the Elderly," Lavizzo-Mourey and Eisenberg note that, to be effective as a means of preventing negative or unintended effects from drug use, therapeutic drug utilization review programs must involve the professional community in the development of the review criteria.

Dispensing Controls

Some major pharmaceutical purchasers may also regulate drug utilization at the pharmacy level by implementing dispensing controls. One dispensing control is a limit on the quantity of drugs that pharmacists may dispense. A common dispensing limit is a 34-day supply. Under this dispensing limit, if the beneficiary needs to use the drug for more than 34 days, he or she will have to obtain a refill of the prescription.

In addition to dispensing limits, some major pharmaceutical purchasers told us they require pharmacies to consult an electronic data base to verify a beneficiary's eligibility to receive drugs and the amount of copayment the beneficiary must pay. One of these major pharmaceutical purchasers that also requires prior authorization for non-formulary drugs told us the data base allows the pharmacist to determine, before dispensing, whether the drug is on the formulary. If the drug is not on the formulary, the pharmacist can call either the physician, for authorization to dispense a different drug, or the major pharmaceutical purchaser, to receive authorization to dispense the non-formulary drug. If a major pharmaceutical purchaser allows therapeutic substitution, the data base may also allow the pharmacist to identify appropriate therapeutic substitutes. Computerized beneficiary files may also allow the pharmacist to assess the appropriateness of a given drug therapy for a beneficiary in relation to other prescription drugs the beneficiary may already be using.

Copayments

Major pharmaceutical purchasers sometimes require their members or beneficiaries to share the cost of each prescription they receive by making a small cash payment or a copayment to the pharmacy at the time of purchase. For the purchasers we surveyed, these copayments ranged from no copayment to \$12 per prescription. At least one of the major pharmaceutical purchasers we surveyed requires a higher copayment if a member or beneficiary receives a brand name drug when a less expensive generic drug is available.

In their 1990 article "Experience of State Drug Benefit Programs," Soumerai and Ross-Degnan point out that copayments are designed to reduce beneficiaries' use of unnecessary drugs, and evidence exists that they do reduce drug use. In their 1984 article "The Effect of a Medicaid Drug Copayment Program on the Utilization and Cost of Prescription Services," Nelson Jr., et al., reported that copayments appeared to have decreased the number of prescriptions per beneficiary when South Carolina

implemented a 50 cents-per-prescription copayment for Medicaid beneficiaries. However, Soumerai and Ross-Degnan also note that it is unlikely that many patients have enough information about their prescriptions to decide which are necessary and which are not, and thus, a copayment could result in patients not receiving needed care.

Pharmacy Reimbursement Limits

Some major pharmaceutical purchasers will cover a beneficiary's prescription only if the patient fills the prescription at a pharmacy with which the major pharmaceutical purchaser has a contract (contract pharmacy). These contracts limit pharmacy reimbursements by specifying a formula by which the major pharmaceutical purchaser will reimburse the pharmacy for filling members' or beneficiaries' prescriptions.

One common reimbursement limit is the average wholesale price (AWP) of the drug less a percentage discount plus a dispensing fee. The AWP is a composite price set by manufacturers and reported in commercial publications. In a 1989 report, the Office of the Inspector General of the federal Department of Health and Human Services determined that the AWP is, on average, at least 15 percent greater than the actual price pharmacies pay to acquire drugs. Some major pharmaceutical purchasers require contract pharmacies to provide a fixed percentage discount off the AWP and, then, add a dispensing fee to compensate the pharmacy for overhead. For example, if a major pharmaceutical purchaser had a contract to reimburse a pharmacy for 100 tablets of a drug at an AWP of \$10 minus 10 percent plus a dispensing fee of \$3.50, the major pharmaceutical purchaser would compute the reimbursement price for the drug as follows:

Commercially published AWP for 100 tablets of the drug	\$10.00
Minus 10 percent discount	(1.00)
<hr/>	
Subtotal	9.00
<hr/>	
Plus dispensing fee	3.50
<hr/>	
Total reimbursement for 100 tablets of the drug	\$12.50

According to one of the major pharmaceutical purchasers we surveyed, pharmacies are willing to enter into these contract reimbursement formulas because the major pharmaceutical purchaser can provide the pharmacy with an increased volume of business.

In addition to reimbursement formulas based on the AWP, at least two of the major pharmaceutical purchasers we surveyed set a maximum allowable cost (MAC) for generic drugs since these drugs are available from several sources at varying prices. The MAC is the highest price the major pharmaceutical purchaser will reimburse the pharmacy for a generic drug. The two major pharmaceutical purchasers establish the MAC for a given drug by reviewing prices charged by various manufacturers of generic drugs.

Negotiated Price Discounts

Some major pharmaceutical purchasers told us they negotiate contracts for price discounts directly with prescription drug manufacturers. In these instances, the purchasers' primary tool for negotiating discounts with prescription drug manufacturers is the purchasers' ability to influence the volume of sales of a manufacturer's product. Also, purchasers may use their formularies and their prescriber education programs to encourage the use of a particular prescription drug or a particular manufacturer's brand of a multiple-source prescription drug and, thus, generate increased sales volume for that drug.

In addition to volume purchasing, some major pharmaceutical purchasers told us that they may enter into drug bundling agreements with manufacturers to achieve greater discounts. According to one of the major pharmaceutical purchasers we surveyed, in a bundling agreement, a manufacturer agrees to provide a discount on one prescription drug, usually a single-source drug, only if the major pharmaceutical purchaser also agrees to purchase or include on its formulary other drugs produced by the manufacturer. One of the hospital buying groups we surveyed purchases non-drug items such as medical, surgical, laboratory, dietary, and radiology supplies and may bundle all of these items plus drugs into one discount purchase agreement. However, some major pharmaceutical purchasers told us they avoid entering bundling agreements because they believe bundling limits their ability to negotiate the best possible price for each drug.

Finally, one major pharmaceutical purchaser we surveyed mentioned other factors it believes are key to successfully negotiating price discounts with prescription drug manufacturers. These include the ability of the purchaser to make a long-term commitment to the manufacturer to convince the manufacturer that it is a credible business partner and will pay all its bills on schedule, and to assure the manufacturer that it will not buy prescription drugs at the discounted price and then resell them to other hospitals or other countries for a profit. Another factor is a good working relationship between the purchaser and the manufacturer.

According to the major pharmaceutical purchasers we surveyed, negotiated discount contracts may take different forms. Contracts may be single year or multiple year. Some contracts guarantee a fixed price for the life of the contract. In addition, multiple-year contracts may contain provisions that allow either party to renegotiate the contract terms during the life of the contract in response to changing circumstances. Contracts may offer per unit discounts that increase in size with increasing volumes of prescription drugs purchased.

A major pharmaceutical purchaser may receive the reduced price in a variety of ways. If a purchaser operates its own pharmacies, it may simply purchase the prescription drugs directly from the manufacturer at the reduced price. However, some manufacturers only sell through wholesalers. In some cases, a wholesaler may agree to sell the prescription drugs to the purchaser at the discounted price negotiated between the manufacturer and the purchaser. The wholesaler later bills the manufacturer for the discount provided to the purchaser. One of the purchasers we surveyed told us it facilitates this type of payment arrangement by entering into prime vendor agreements, dealing exclusively with one or two wholesalers. Alternatively, the purchaser may buy the prescription drugs from the wholesaler at the wholesaler's regular price and then receive a rebate from the drug manufacturer for the difference between the price the purchaser paid to the wholesaler and the negotiated price.

**How Some
Major
Purchasers
Apply Cost
Controls**

The participants in our survey of major pharmaceutical purchasers use a variety of methods to manage the overall cost of the drug benefits they provide to patients. However, some of the major pharmaceutical purchasers we surveyed are more active than others in applying utilization and price controls to manage their drug benefits. A more active purchaser may employ more utilization and price controls in managing the use of drugs in its facilities. The more active the purchasers are in managing their drug benefits, the more opportunities become available to control drug expenditures.

The major pharmaceutical purchasers we surveyed that merely acquired drugs for their organizations but did not dispense drugs, such as the three governmental organizations or the two buying groups, typically focused their efforts in lowering drug costs by attempting to lower the price of the drugs they were purchasing. Table 1 shows the strategies that the government organizations and hospital buying groups we surveyed may use to control their drug expenditures.

Table 1 Utilization and Price Controls Used by Government Organizations and Hospital Buying Groups

Utilization and Price Controls	Department of Veterans Affairs	Department of General Services	Los Angeles County	Hospital Buying Group A	Hospital Buying Group B
Manufacturers' price discount	Yes	Yes	Yes	Yes	Yes
Product bundling	No	No	Yes	Yes	Yes
Drug formulary	NA	NA	NA	NA	NA
Prior authorization	NA	NA	NA	NA	NA
Generic substitution	No	No	No	Yes	Yes
Therapeutic substitution	No	No	No	No	No
Prescriber education	NA	NA	NA	Yes	No
Prescriber financial incentives	NA	NA	NA	No	No
Electronic data base	NA	NA	NA	NA	NA
Drug utilization review	NA	NA	NA	NA	NA
Contract pharmacy	NA	NA	NA	NA	NA
Reimbursement limits	NA	NA	NA	NA	NA
Patient copayments	NA	NA	NA	NA	NA

Source: Surveys conducted by the Office of the Auditor General.

Note: NA refers to utilization and price controls that may not have been used by government organizations or hospital buying groups because these entities did not dispense drugs.

These purchasers focused on the price of drugs they purchased by competitively bidding the price of individual drug items. Three purchasers stated that they negotiate price discounts by entering “bundling” agreements, agreeing to purchase multiple-source drugs from a particular vendor in exchange for a price discount on that vendor’s single-source drug. (Vendors consist of manufacturers and wholesalers.) One of the three purchasers stated it sometimes entered purchasing agreements with drug vendors who offered rebates that returned a percentage of the

purchase price to the purchaser or offered lower unit prices. Price rebates were sometimes tied to the volume of the drug purchased. Volume-based pricing allowed the purchaser to pay a lower unit price as its purchases increased.

The hospitals and health maintenance organizations (HMOs) we surveyed employed both utilization and price controls to control the use of drugs in their facilities and to manage the overall cost of their drug benefits. Table 2 shows the strategies that the hospitals and HMOs we surveyed use to control their drug expenditures. One of the five HMOs we surveyed delivers its services through two different membership plans. This HMO is identified in Table 2 as A1 and A2.

Table 2 Utilization and Price Controls Used by Hospital and Health Maintenance Organizations (HMOs)

Utilization and Price Controls	Hospital A	Hospital B	HMO A1	HMO A2	HMO B	HMO C	HMO D	HMO E
Manufacturer price discount	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Product bundling	No	Yes	Yes	Yes	No	No	No	No
Drug formulary	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Prior authorization	Yes	Yes	Yes	Yes	Yes	No	No	NA
Generic substitution	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Therapeutic substitution	No	Yes	Yes	No	No	No	Yes	No
Prescriber education	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Prescriber financial incentives	No	No	No	No	Yes	Yes	Yes	No
Electronic data base	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Drug utilization review	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Contract pharmacy	No	No	No	Yes	Yes	Yes	No	No
Reimbursement limits	NA	NA	NA	Yes	Yes	Yes	NA	Yes
Patient copayments	No	No	Yes	Yes	Yes	Yes	Yes	Yes

Source: Surveys conducted by the Office of the Auditor General.

Hospitals employ both utilization and pricing strategies to control the use of drugs in their facilities and to contain the growth of their drug expenditures. Both of the hospitals we surveyed stated they manage a restricted formulary that lists the drugs approved for use in the hospital. Both hospitals require physicians to submit authorization requests before the hospital pharmacy will dispense a prescription for a non-formulary drug. Also, both of the hospitals require the hospital pharmacy to substitute generic drugs for brand name items unless the physician instructs otherwise. One of the two hospitals allows pharmacists to substitute therapeutically equivalent drugs. Both hospitals conduct some form of physician education to advise physicians of the therapeutic value of drugs. Both hospitals monitor drug utilization with an on-line data system.

The HMOs we surveyed also employ utilization and pricing strategies to control the use of drugs by plan members and to contain the growth of their drug expenditures. Three of the HMOs we surveyed did not operate their own pharmacies. Two of the three HMOs had entered into agreements with selected pharmacies throughout the State where the beneficiaries of these HMOs could get their prescriptions filled. The two HMOs that used these contract pharmacies controlled drug utilization by limiting the amount they reimbursed contract pharmacies for dispensing drugs. Such agreements were one way HMOs encouraged pharmacies to dispense the lowest priced drug when medically appropriate. The two HMOs that used contract pharmacies to dispense drugs to patients had implemented maximum allowable prices for some generic drugs. Maximum allowable prices encourage pharmacies to take the cost of the drug into account when dispensing.

Chapter 2 Attempts To Control the Growth in Medi-Cal Drug Expenditures

Chapter Summary

The California Medical Assistance Program (Medi-Cal) uses both utilization and price strategies in its attempt to stem the increase in its drug expenditures. The establishment of a restrictive formulary, the requirement for prior authorization when non-formulary drugs are prescribed, the requirement that generic drugs be dispensed whenever possible, and the imposition of dispensing, prescribing, and payment restrictions are all examples of utilization controls instituted by Medi-Cal. However, as its primary way of controlling the price of pharmaceuticals, Medi-Cal uses maximum limits on the amount it reimburses pharmacies serving Medi-Cal patients. Also, recently, the Department of Health Services (department) implemented a drug discount program designed to reduce the prices Medi-Cal pays for drugs. Through this program, the department negotiates directly with drug manufacturers for rebates on pharmaceuticals. The department estimates the drug discount program will save Medi-Cal \$3.3 million (\$1.65 million in General Fund moneys and \$1.65 million in federal moneys) in fiscal year 1990-91. However, this estimate does not take into account \$659,000 in budgeted costs associated with the operation of the drug discount program.

Background

Under Medi-Cal, beneficiaries may receive prescription drugs that are included on a list established by the department. This list is known as the Medi-Cal list of contract drugs and includes drugs from most therapeutic categories. Therapeutic categories are classifications of drugs that address specific medical problems. For example, the list of contract drugs includes such therapeutic categories as antibiotics and cardiac and gastrointestinal drugs. Once drugs on the list are prescribed by licensed practitioners,

Medi-Cal beneficiaries obtain them through providers, usually pharmacists. When a provider supplies a prescribed drug to a beneficiary, the provider also submits a claim for payment for services to a non-governmental fiscal intermediary who processes Medi-Cal claims for reimbursement on behalf of the State. The fiscal intermediary, using established criteria, determines whether a provider's claim should be paid.

Restrictive Formulary

The department has made numerous attempts to stem the growth of Medi-Cal drug expenditures. For example, the department has attempted to control drug expenditures through the use of a list of drugs that it prefers be prescribed to Medi-Cal beneficiaries. Established under Title 22 of the California Code of Regulations, this list was known as the formulary. Legislation adopted in 1990 changed the name of the Medi-Cal formulary to the list of contract drugs. Medi-Cal's formulary contained more than 500 drugs and identified drugs that could be provided to Medi-Cal beneficiaries without receiving prior authorization from the department. The availability of many drugs listed on the formulary was also limited by restricting such items as the quantity, strength, and dosage forms and the medical condition to be treated through a given drug. Any additions of drugs to the formulary were done through the adoption of state regulation. On July 1, 1990, Medi-Cal's drug formulary became known as the list of contract drugs. With the establishment of the drug discount program on July 31, 1990, the addition of a drug to the list of contract drugs no longer requires the adoption of a state regulation.

Prior Authorization

The department requires that providers seek prior authorization for certain drugs before these drugs are dispensed to Medi-Cal beneficiaries. When a doctor prescribes a drug for a Medi-Cal beneficiary that is not on the list of contract drugs, the provider, generally a pharmacist, must receive authorization to seek reimbursement for the cost of the drug. The patient's physician or pharmacist may request authorization from a regionally based Medi-Cal consultant, who is a licensed pharmacist, through a treatment authorization request. Authorization may only be granted for drugs that are medically necessary and are the lowest priced to meet the beneficiary's medical needs.

Required Generic Substitution	Medi-Cal also uses generic substitution to control drug costs. Generic substitution reduces the cost per prescription for drugs available from multiple suppliers. According to Title 22 of the California Code of Regulations, pharmacists are required to substitute the lowest priced generic drug for the drug that was prescribed, provided the pharmacists have the less expensive generic drug in stock and the drug meets the medical needs of the beneficiary.
Copayment	With certain exceptions, Medi-Cal recipients are obligated to copay \$1.00 for each drug prescription or refill. However, the collection of a copayment by pharmacists is optional and may be either collected and retained or waived. However, a pharmacist cannot deny services to an individual solely because of that person's inability to copay. Any copayment collected by a pharmacist is retained by the pharmacist and is in addition to any reimbursement due for services rendered under Medi-Cal. According to the department, there is no requirement for pharmacies to report on copayment collections. Consequently, there is no information available to determine the extent to which copayments are collected.
Dispensing, Prescribing, and Payment Restrictions	To limit Medi-Cal drug expenditures, the department has also placed restrictions on how prescription drugs are dispensed, prescribed, and paid for under Medi-Cal. Medi-Cal limits the quantity of each prescription, the number of prescriptions that can be filled within a certain period, and the specific use of drugs included on the list of contract drugs. According to Title 22 of the California Code of Regulations, Medi-Cal beneficiaries cannot receive more than a 100-day supply of a prescription drug from a provider, except under certain circumstances. In addition, the list of contract drugs identifies drugs that must be dispensed in minimum quantities of 100 tablets or capsules. This restriction generally applies to drugs that require long-term use. As a way of

enforcing the restriction, Medi-Cal will fully pay the provider only when a minimum quantity of at least 100 tablets or capsules is furnished to the beneficiary.

In addition, many drugs on the list of contract drugs are subject to other restrictions. Although Medi-Cal does not directly limit the number of prescriptions that can be given to Medi-Cal beneficiaries, it does restrict the amount of payment per drug that it makes during a specified period. After pharmacists fill prescriptions for drugs on the list of contract drugs, they receive payment from Medi-Cal for both the service of dispensing the drug to the patient and the cost of the ingredients in the drug. To prevent pharmacists from overdispensing certain drugs, Medi-Cal will not pay the dispensing fee when the same drug is provided to the same beneficiary more than three times in a 75-day period.

Finally, Medi-Cal restricts the use of some drugs on the list of contract drugs to specific medical problems. For example, the drug nalidixic acid is restricted for use to urinary and prostatic infections; Medi-Cal will not pay for this drug if it is provided to treat other medical problems unless prior authorization has been received. Pharmacists must keep records that meet state regulations for dispensed drugs subject to these specific-use restrictions.

Drug Utilization Review

In the Medi-Cal program, Chapter 1340 of the Statutes of 1987 established a pilot drug utilization review, which the department is responsible for administering. To operate the drug utilization review, the department has contracted with the Virginia Computer Company, which, in turn, entered into a contract with the Stanford Research Institute to evaluate the pilot program.

The drug utilization review committee assesses whether a physician should have prescribed (or a pharmacy should have dispensed) a particular medication given the medication's suggested uses, its interactions with other drugs the patient is using, and the patient's diagnosis. If the committee finds that physicians or pharmacists may have prescribed or dispensed

medications inappropriately, the committee notifies the physicians or pharmacists of its concern. Through this type of intervention, the program is intended to improve the therapeutic outcome for Medi-Cal beneficiaries.

In accordance with Chapter 1340 of the Statutes of 1987, our office was also responsible for assessing the cost-effectiveness of the pilot drug utilization review. To do this review, we contracted with the consulting company of Ernst and Young. In its May 1991 report, Ernst and Young concluded that the program resulted in the decreased use of drugs, outpatient services, and hospital care for a small group of Medi-Cal recipients during the review period. However, the cost savings associated with the reductions in services were too small to prove the cost-effectiveness of the program.

Reimbursement Limits

A reimbursement limit is a ceiling on what Medi-Cal will reimburse a pharmacist for a particular drug the pharmacist has provided to a Medi-Cal beneficiary. Federal regulations require states to base reimbursement for drugs on the best estimate of the price generally and currently paid by providers for a drug sold by a particular manufacturer or labeler. As a result, to limit drug costs, Medi-Cal has established several reimbursement limits, depending on the drug dispensed and the drug's manufacturer, for pharmacies dispensing prescriptions to Medi-Cal beneficiaries. In general, pharmacies are reimbursed for a drug's ingredient cost plus a dispensing fee. According to a department official, a dispensing fee was established to provide participating pharmacists with a reasonable reimbursement to cover their overhead and profit.

California regulation states that generally the cost for dispensed drugs should equate to the lowest of four reimbursement limits: the pharmacies usual and customary charges to the general public; the Estimated Acquisition Cost (EAC) plus a dispensing fee; the Maximum Allowable Ingredient Cost (MAIC) plus a dispensing fee; or the Federal Allowable Cost (FAC) plus a dispensing fee. With certain exceptions, Medi-Cal reimburses pharmacies a standard dispensing fee of \$4.05 for each prescription filled.

Estimated Acquisition Cost

For all drugs manufactured or distributed by a group of 11 designated pharmaceutical companies, which are identified in regulation, the EAC is the direct price. A pharmacy pays the direct price to one of the 11 manufacturers when purchasing a drug directly from the manufacturer. Medi-Cal's EAC reimbursement limit for the products of these specific manufacturers is the direct price because providers generally buy directly from these manufacturers. In contrast, for all other drugs, the EAC is the average wholesale price (AWP) minus 5 percent. (See page 14 for a definition of average wholesale price.) Medi-Cal's EAC reimbursement limit of the AWP minus 5 percent is applicable to all other products because providers generally purchase these products through wholesalers. By making a distinction between purchases from manufacturers and those from wholesalers, Medi-Cal is able to more accurately capture the price generally and currently paid by providers.

Change in EAC Regulation

Before October 16, 1989, the EAC was defined in California regulation as the AWP or other price the department determines to be the price generally and currently paid by providers for a drug marketed or sold in a standard package. However, the practice of reimbursing pharmacies at an undiscounted AWP was questioned by both the inspector general of the federal Department of Health and Human Services and the federal Health Care Financing Administration (HCFA). In a 1989 report, the inspector general cited a report issued in 1984 entitled Changes to the Medicaid Prescription Drug Program Could Save Millions. The 1984 report concluded that, on average, pharmacies buy drugs for 15.9 percent below the AWP. In August 1989, the HCFA provided clarification regarding the use of the published AWP as a State's determination of the EAC. The HCFA pointed out that the EAC means a state's best estimate of the price generally and currently paid by providers. Further, the HCFA pointed out the preponderance of evidence demonstrating that the AWP overstates the prices that pharmacies actually pay for drugs by as much as 10 to 20 percent because the AWP does not reflect discounts, premiums, special offers, or other incentives that manufacturers or wholesalers provide to pharmacists.

Consequently, the HCFA stated that, without valid documentation to the contrary, a published AWP level as a state determination of the EAC without a significant discount being applied would not be an acceptable estimate of prices generally and currently paid by providers.

Moreover, in October 1989, the inspector general issued a report entitled Uses of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program. In this report, the inspector general found that, on average, pharmacies were buying drugs for 15.5 percent below the AWP and concluded that the AWP was not a meaningful payment level and that it should not be used for making reimbursements. The inspector general recommended that the HCFA continue to require state Medicaid agencies, such as Medi-Cal, to discount the AWP when making program reimbursements.

As a result of the HCFA's August 1989 clarification that state Medicaid agencies discount the AWP when making program reimbursements, the department amended the method of reimbursement. In September 1989, an emergency regulation was filed amending California regulations and modifying the definition of the EAC as it relates to Medi-Cal payments to providers of drugs. Consequently, beginning on October 16, 1989, pharmacists providing drugs under the Medi-Cal program where the EAC is the reimbursement limit used and where a direct price does not apply began receiving cost reimbursements at the AWP minus 5 percent instead of at the pre-amendment limit. According to the department, the AWP minus 5 percent was established because it is the State's best estimate of the price generally and currently paid by providers for certain drugs.

Maximum Allowable Ingredient Cost

The MAIC, independently established by the department, is a maximum cost reimbursement limit, or price for certain multiple-source drugs on the Medi-Cal list of contract drugs. According to the department, MAICs are generally established for highly used multiple-source drugs where the difference between

the generic and brand name price is significant. Each MAIC reimbursement limit is established by the department and based on the price of a reference product that the department determines to be generically equivalent in quality to products used by physicians throughout the State. The reference product must be generally available to pharmacies, through customary distribution channels, in sufficient quantities to meet the needs of Medi-Cal.

For example, the department stated that when it established a MAIC for the generic drug allopurinol, it first surveyed the numerous manufacturers that produce allopurinol to obtain therapeutic equivalency data and to determine if their product is available throughout the State. At the same time, the department also obtained each manufacturer's current AWP price for the drug. The MAIC price was then established by selecting from those manufacturers that responded to the survey the lowest or one of the lowest priced therapeutic drugs that met the therapeutic equivalency and availability criteria. MAICs are updated monthly to reflect current marketplace price changes.

Federal Allowable Cost

A FAC, established independently by the federal Department of Health and Human Services (HHS), is an upper limit of payment for certain multiple-source drugs. In effect, the federally required FAC is administered by Medi-Cal in the same manner as the MAICs. The purpose of the FAC upper limits is to take advantage of savings resulting from the availability of less costly, but safe and effective, generic drug substitutes.

The major difference between the FACs and the MAICs is that the HHS periodically issues changes in the FAC list of drugs and respective price limits whereas the MAIC price limits are established and updated monthly by the department. Also, the formula that the HCFA uses in calculating the FACs is different from the process California uses in determining the MAICs, and a difference can exist between the FAC and MAIC prices for the same drug. Generally, the FAC limits are the lower of the two.

When a drug is listed on both the FAC and MAIC price lists, the maximum reimbursement allowed is the lower of the FAC or MAIC.

When medically necessary, approval of payment may be obtained for a product whose price exceeds the FAC or MAIC price limits by requesting prior authorization from a Medi-Cal consultant. For example, the FAC reimbursement limit for 100 tablets of 2 mg strength generic albuterol is \$9.66. However, if medically necessary, Medi-Cal would approve payment for Ventolin, a generically equivalent brand name drug, whose current price is \$29.75.

Variation in Amounts Pharmacies Bill and Are Reimbursed

Areimbursement limit is a ceiling on what Medi-Cal will reimburse a pharmacist for a particular drug the pharmacist has provided to a Medi-Cal beneficiary. However, the amount the pharmacist bills Medi-Cal for filling that prescription may not always coincide with the Medi-Cal reimbursement limit. For example, some pharmacists, who may not know all the reimbursement limits, may simply bill Medi-Cal for the same amount they would charge their other customers. However, reimbursements for drugs covered under Medi-Cal will only be made at the Medi-Cal reimbursement limit.

We surveyed six pharmacists to obtain the amount their pharmacy would charge Medi-Cal for a sample of six multiple-source prescription drugs. (The survey included one pharmacist at a chain pharmacy and one at a pharmacy specializing in providing drugs to skilled nursing facilities.) We then compared the amounts that these pharmacies would charge to Medi-Cal with the amounts for Medi-Cal reimbursement limits to determine whether a significant difference existed between the amount that the pharmacies would have billed and the amount that Medi-Cal would have reimbursed. Table 3 shows the variation in pharmacy charges to Medi-Cal, by drug and manufacturer, for each of the six pharmacies in our sample. In addition, the table reflects the difference in Medi-Cal reimbursement limits.

Table 3
Variations in Medi-Cal Reimbursement Limits

Generic Drug Name Strength Quantity	Pharmacy	Manufacturer	Estimated Acquisition Cost			Maximum Allowable Ingredient Cost ^b	Federal Allowable Cost ^b
			Amount Pharmacy Would Have Charged Medi-Cal ^a	Direct Price	Average Wholesale Price Minus 5 Percent ^b		
Amitriptyline Hydrochloride 50mg 100 tablets	Pharmacy A	Goldline	\$ 7.35		\$ 7.04	\$12.61	\$12.61
	Pharmacy B	Purepac	\$ 8.03	\$12.51	\$12.51	\$12.61	\$12.61
	Pharmacy C	Purepac	\$12.91	\$12.51	\$12.51	\$12.61	\$12.61
	Pharmacy D ^c	Rugby	\$12.61	\$ 8.12	\$ 8.12	\$12.61	\$12.61
	Pharmacy E ^d	Barr	\$ 7.36	\$ 6.96	\$ 6.96	\$12.61	\$12.61
	Pharmacy F	Genava	\$ 7.20	\$ 9.18	\$ 9.18	\$12.61	\$12.61
Chloral Hydrate 500mg 100 tablets	Pharmacy A	Goldline	\$11.70	\$11.18	\$ 9.14		
	Pharmacy B	Goldline	\$ 9.14	\$11.18	\$ 9.14		
	Pharmacy C	Goldline	\$ 9.44	\$11.18	\$ 9.14		
	Pharmacy D ^c	Squibb	\$ 9.14		\$ 9.14		
	Pharmacy E ^d	Goldline	\$11.80	\$11.18	\$ 9.14		
	Pharmacy F	H.L. Moore	\$ 9.15	\$10.20	\$ 9.14		
Acetaminophen with Codeine 30mg/300-325mg 45 tablets/capsules	Pharmacy A	Rugby	\$ 8.62	\$ 8.25	\$ 7.43	\$ 6.14	\$ 6.14
	Pharmacy B	Parmed	\$ 6.14	\$ 7.70	\$ 7.43	\$ 6.14	\$ 6.14
	Pharmacy C	Parmed	\$ 6.44	\$ 7.70	\$ 7.43	\$ 6.14	\$ 6.14
	Pharmacy D ^c	Purepac	\$ 6.15	\$ 7.43	\$ 7.43	\$ 6.14	\$ 6.14
	Pharmacy E ^d	Lemmon	\$ 8.13	\$ 7.23	\$ 7.43	\$ 6.14	\$ 6.14
	Pharmacy F	Purepac	\$ 6.14	\$ 7.43	\$ 7.43	\$ 6.14	\$ 6.14
Mecizine Hydrochloride 25mg 100 tablets	Pharmacy A	Rugby	\$ 8.40	\$ 8.04	\$ 7.27	\$ 6.15	\$ 6.15
	Pharmacy B	Goldline	\$ 6.15	\$ 7.76	\$ 7.27	\$ 6.15	\$ 6.15
	Pharmacy C	Sidmark	\$ 6.45	\$ 6.41	\$ 7.27	\$ 6.15	\$ 6.15
	Pharmacy D ^c	Rugby	\$ 5.24	\$ 8.04	\$ 7.27	\$ 6.15	\$ 6.15
	Pharmacy E ^d	Major	\$ 7.82	\$ 7.95	\$ 7.27	\$ 6.15	\$ 6.15
	Pharmacy F	Geneva	\$ 6.15	\$ 7.81	\$ 7.27	\$ 6.15	\$ 6.15
Promethazine with Phenylephrine & Codeine 480cc	Pharmacy A	Geneva	\$12.41	\$11.89	\$11.80	\$10.96	\$10.96
	Pharmacy B	Geneva	\$10.95	\$11.89	\$11.80	\$10.96	\$10.96
	Pharmacy C	Barre	\$11.25	\$12.03	\$11.80	\$10.96	\$10.96
	Pharmacy D ^c	Barre	\$ 9.67	\$12.03	\$11.80	\$10.96	\$10.96
	Pharmacy E ^d	Geneva	\$14.38	\$11.89	\$11.80	\$10.96	\$10.96
	Pharmacy F	Not stocked					

Generic Drug Name Strength Quantity	Pharmacy	Manufacturer	Amount Pharmacy Would Have Charged Medi-Cal ^a	Estimated Acquisition Cost		
				Direct Price	Average Wholesale Price Minus 5 Percent ^b	Maximum Allowable Ingredient Cost ^b Federal Allowable Cost ^b
Propranolol Hydrochloride 40mg 100 tablets	Pharmacy A Pharmacy B Pharmacy C Pharmacy D ^c Pharmacy E ^d Pharmacy F	Goldline Warner-Chilcott Warner-Chilcott Purepac Roxane Lederle	\$ 9.85 \$ 5.70 \$ 6.08 \$ 5.78 \$ 8.56 \$ 5.78	\$ 9.42 \$20.64 \$20.64 \$12.32 \$11.16 \$18.60	\$13.08 \$13.08 \$13.08 \$13.08 \$12.08 \$13.08	\$ 5.78 \$ 5.78 \$ 5.78 \$ 5.78 \$ 5.78 \$ 5.78

Source: Telephone survey of selected pharmacists conducted in June 1991, and data supplied by staff at the Department of Health Services.

^aIncludes a dispensing fee

^bIncludes a dispensing fee of \$4.05

^cChain pharmacy

^dPharmacy specializing in providing drugs to skilled nursing facilities

Our survey of pharmacists revealed that a significant difference exists in the amount the pharmacies would have billed Medi-Cal for the same prescription drug. Further, a significant difference exists in the amount Medi-Cal would have reimbursed six different pharmacies for the same prescription drug.

However, Medi-Cal does not always reimburse the pharmacies the amount that the pharmacies bill. Rather, Medi-Cal reimburses the pharmacy the lower of what the pharmacy normally charges its customers or the applicable reimbursement limit. In Table 4, we compare the amounts that each of the pharmacies would have been reimbursed for each of the six sample prescription drugs.

Table 4

**Variations in Medi-Cal Reimbursement
Amounts to Six Pharmacies**

Pharmacy	Generic Drug Name	Manufacturer	Medi-Cal Reimbursement Amount	Medi-Cal Reimbursement Limit ^a
Pharmacy A	Amitriptyline Hydrochloride	Goldline	\$ 7.04	AWP-5%
	Chloral Hydrate	Goldline	9.14	MAIC
	Acetaminophen with Codeine	Rugby	6.14	FAC
	Meclizine Hydrochloride	Rugby	6.15	FAC
	Promethazine with Phenylephrine & Codeine	Geneva	10.96	FAC
	Propranolol Hydrochloride	Goldline	5.78	FAC
Total			\$45.21	
Pharmacy B	Amitriptyline Hydrochloride	Purepac	\$ 8.03	Amount billed
	Chloral Hydrate	Goldline	9.14	MAIC/Amount billed
	Acetaminophen with Codeine	Parmed	6.14	FAC/Amount billed
	Meclizine Hydrochloride	Goldline	6.15	FAC/Amount billed
	Promethazine with Phenylephrine & Codeine	Geneva	10.95	Amount billed
	Propranolol Hydrochloride	Warner-Chilcott	5.70	Amount billed
Total			\$46.11	
Pharmacy C	Amitriptyline Hydrochloride	Purepac	\$12.51	AWP-5%
	Chloral Hydrate	Goldline	9.14	MAIC
	Acetaminophen with Codeine	Parmed	6.14	FAC
	Meclizine Hydrochloride	Sidmark	6.15	FAC
	Promethazine with Phenylephrine & Codeine	Barre	10.96	FAC
	Propranolol Hydrochloride	Warner-Chilcott	5.78	FAC
Total			\$50.68	
Pharmacy D ^b	Amitriptyline Hydrochloride	Rugby	\$ 8.12	AWP-5%
	Chloral Hydrate	Squibb	9.14	MAIC/Amount billed
	Acetaminophen with Codeine	Purepac	6.14	FAC
	Meclizine Hydrochloride	Rugby	5.24	Amount billed
	Promethazine with Phenylephrine & Codeine	Barre	9.67	Amount billed
	Propranolol Hydrochloride	Purepac	5.78	FAC/Amount billed
Total			\$44.09	
Pharmacy E ^c	Amitriptyline Hydrochloride	Barr	\$ 6.96	AWP-5%
	Chloral Hydrate	Goldline	9.14	MAIC
	Acetaminophen with Codeine	Lemmon	6.14	FAC
	Meclizine Hydrochloride	Major	6.15	FAC
	Promethazine with Phenylephrine & Codeine	Geneva	10.96	FAC
	Propranolol Hydrochloride	Roxane	5.78	FAC
Total			\$45.13	
Pharmacy F	Amitriptyline Hydrochloride	Geneva	\$ 7.20	Amount billed
	Chloral Hydrate	H.L. Moore	9.14	MAIC
	Acetaminophen with Codeine	Purepac	6.14	FAC/Amount billed
	Meclizine Hydrochloride	Geneva	6.15	FAC/Amount billed
	Promethazine with Phenylephrine & Codeine	Not stocked		
	Propranolol Hydrochloride	Lederle	5.78	FAC/Amount billed

^aAWP-5% = Average wholesale price minus 5 percent

MAIC = Maximum allowable ingredient cost

FAC = Federal allowable cost

Amount billed = Amount that would have been billed to Medi-Cal by pharmacy

^bChain pharmacy

^cPharmacy specializing in providing drugs to skilled nursing facilities

Table 4 shows that, when the reimbursement amounts for all six prescription drugs in our sample are combined, one pharmacy would have been reimbursed at an amount significantly less than the pharmacy that would have received the highest total reimbursement. The lowest total reimbursement of \$44.09 would have been to Pharmacy D, and the highest total reimbursement of \$50.68 would have been to Pharmacy C, a difference of \$6.59, or 15 percent. Pharmacy D's reimbursement would have been less primarily because reimbursement for the prescription drug amitriptyline hydrochloride, at the AWP minus 5 percent, was \$8.12 whereas the reimbursement to Pharmacy C for the same drug, also at the AWP minus 5 percent, would have been \$12.51, a difference of \$4.39. This difference occurred because pharmacies D and C obtain amitriptyline hydrochloride from different manufacturers.

The HCFA has reported that most large chains, such as Pharmacy D in our sample, have altered the traditional market channels by creating their own warehouses to replace, in many ways, the wholesaler. By doing this, a chain can buy in much larger quantities than individual pharmacies, resulting in lower prices because of volume discounts. Because Pharmacy D, a chain pharmacy, would have been reimbursed the lowest total of \$44.09 when all six drugs are combined, the State would have shared in the savings that Pharmacy D was able to effect.

The Medi-Cal Drug Discount Program

In July 1990, legislation was passed establishing a new strategy designed to slow the growth of Medi-Cal drug expenditures. In accordance with Chapters 456, 457, 1643, and 1694 of the Statutes of 1990, the department adopted, on a pilot basis, the drug discount program, which is effective until January 1, 1993. The drug discount program allows the department to begin negotiating discounts on drugs paid for through Medi-Cal.

According to the department's acting chief negotiator, the primary objective of the drug discount program is to obtain significant discounts on the price of pharmaceuticals. To

accomplish this, the department can take advantage of discount prices that manufacturers provide to other high-volume purchasers of drugs. Section 14105.33 of the Welfare and Institutions Code authorizes the department to enter into contracts with manufacturers of drugs for rebates on drugs purchased through Medi-Cal. The amount of a rebate, which is defined in Section 14105.31 of the Welfare and Institutions Code as an equalization payment amount, is based on the difference between the manufacturer's price typically charged to wholesalers and the manufacturer's best price. Best price is defined as the price negotiated between the department and the manufacturer or the lowest price the manufacturer sells the drug for to another entity that has a contract with the manufacturer.

By March 1991, the department had negotiated rebate contracts with 15 drug manufacturers, and it has estimated that these contracts will save Medi-Cal \$3.3 million (\$1.65 million in General Fund moneys and \$1.65 million in federal moneys) during fiscal year 1990-91. However, in our June 1991 report entitled A Review of the Department of Health Services' Estimate of Savings Resulting From the Drug Discount Program (Report P-113), we indicated that the department's \$3.3 million estimate did not take into consideration the budgeted \$659,000 in state costs associated with operating the drug discount program.

Another objective of the drug discount program is to make a greater selection of drugs available to Medi-Cal beneficiaries. Before this program was established, drugs for which Medi-Cal would reimburse could be added only by regulation, a process that, for two drugs we researched, took approximately 15 months. Now the department may add new single-source drugs to the list of contract drugs when the department and the manufacturers negotiate rebate contracts, with certain exceptions. For two drugs we researched, the process of adding these drugs through negotiation took approximately four months for one drug and seven months for the other.

Under the state regulation process, manufacturers or other interested parties petitioned the department to add a drug to the formulary. The department then drafted a proposed state regulation that would have the effect of adding the drug to the formulary. The department's medical therapeutics and drug advisory committee would then evaluate the drug based on the safety, efficacy, cost, need, and potential for misuse and make written recommendations to the director of the department. The committee then was required to make public its recommendations about adding the drug to the formulary. After the recommendations were made public, the director made the decision to add the drug or not. If the director determined that the drug should be added, the final regulation was sent for review to the Office of Administrative Law (office). The office ensured all legal and procedural requirements were followed in the adoption of the new regulation. Once the office approved the regulation, it generally became effective 30 days after the office filed the regulation with the secretary of State.

Under the drug discount program, it is not necessary to adopt a new state regulation to add a drug to the list of contract drugs. A manufacturer of a single-source drug will petition the department to add a drug to the list. Then, according to California law, a Medi-Cal drug advisory committee will evaluate the drug based on the safety, efficacy, cost, need, and potential for misuse. In addition, department staff also evaluate the drug based on the same criteria. However, according to the department's deputy director of medical care services, as of July 1991, a Medi-Cal drug advisory committee has not yet been appointed. At the present time, only the department staff are performing the evaluation. After the drug has been evaluated, the department schedules a time for the department and the manufacturer to negotiate a rebate contract. After negotiations are conducted, the director of the department decides whether the petitioned drugs should be added to the list of contract drugs. Once the director agrees that the drug should be added to the list, it may take from 60 to 90 days to actually add the drug to the list of contract drugs.

According to the department's pharmaceutical program consultant, since the implementation of the drug discount program, 35 drugs have been added to the list of contract drugs, as of August 1, 1991. The drug discount program has not replaced or eliminated any of the utilization or price controls that were part of the Medi-Cal drug benefit before the implementation of the program.

Federal Cost Controls

The federal government has also taken steps to contain the prescription drug expenditures of state Medicaid programs. The federal Health Care Financing Administration (HCFA) oversees the Medicaid program, which, together with state governments, provides basic health services, including prescription drugs, to public assistance recipients, low-income individuals and families, and medically needy individuals. Through Medicaid, the federal government provides matching funds to states that have instituted medical care programs, such as Medi-Cal. Through the Omnibus Budget Reconciliation Act of 1990, enacted on November 5, 1990, the federal government implemented its own version of a drug discount program. This legislation requires drug manufacturers wanting to do business with state Medicaid programs, such as Medi-Cal, to enter into rebate agreements with the federal government, which provides a discount on the price of prescription drugs provided to program recipients. However, Section 1927(a)(i) of Title XIX of the Social Security Act, included in the Omnibus Budget Reconciliation Act of 1990, does include an exception to this provision. Namely, states may be authorized to enter directly into their own agreements with drug manufacturers if the state agreements meet certain federal criteria.

In November 1990, the department formally requested that the HCFA waive the requirement that the department participate in the federal program. The department requested this waiver so that it could continue to operate its own drug discount program through which it negotiates agreements directly with drug manufacturers to obtain rebates. As of July 1991, the HCFA still

had not reached a decision regarding the waiver. However, the HCFA did contact the department in April 1991, indicating the waiver would be granted if the discounts Medi-Cal would receive from drug manufacturers under its drug discount program would be at least as great as those it would receive under the federal drug discount program. Moreover, the HCFA indicated the department is responsible for providing to the HCFA regional office in San Francisco requests for approval for proposed agreements between the department and drug manufacturers. An HCFA official indicated that, as of July 1991, Medi-Cal had submitted 16 agreements between the department and drug manufacturers for approval. However, according to the official, the HCFA had not yet announced a final decision concerning approval of these agreements.

**Medi-Cal Uses
Most of the
Same Cost
Controls as
Other Major
Pharmaceutical
Purchasers**

As we discussed in Chapter 1 of our report, our survey of major pharmaceutical purchasers revealed they use many utilization and price strategies to control the cost of pharmaceuticals. Medi-Cal uses most of the same utilization and price strategies as the major pharmaceutical purchasers in its attempt to stem the increase in its drug expenditures, but not all of the controls the major pharmaceutical purchasers use would be suitable for use by Medi-Cal because of Medi-Cal's system for delivering services. For example, at least one of the major pharmaceutical purchasers we surveyed buys drugs in bulk quantities. However, according to the department, Medi-Cal is not currently involved in buying drugs in bulk quantities. Instead, beneficiaries obtain prescription drugs at those California pharmacies that serve Medi-Cal beneficiaries. Any consideration of additional strategies Medi-Cal might use to lower its drug costs must take into account how Medi-Cal delivers health services to its beneficiaries since some strategies might require an overhaul of this delivery system.

We conducted this review under the authority vested in the auditor general by Section 10500 et seq. of the California Government Code and according to generally accepted governmental auditing standards. We limited our review to those areas specified in the audit scope section of this report.

Respectfully submitted,



KURT R. SJOBERG
Auditor General (acting)

Date: August 26, 1991

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Appendix A Canadian Drug Pricing Policies and Utilization Controls

In its 1990 report entitled Strategies To Reduce Medicaid Drug Expenditures, the Office of the Inspector General of the federal Department of Health and Human Services reported that, for 48 brand name drugs, the United States' average wholesale price was 62 percent higher than the average of the prices in two Canadian provinces. To determine some of the strategies that the Canadian federal and provincial governments use to control drug prices, we contacted Canadian government officials at the federal and provincial levels.

The Patented Medicine Price Review Board (board) is a Canadian federal agency that reviews patented medicine prices to ensure that the prices are not excessive. The board reports its findings on drug prices, along with information about pharmaceutical price trends and pharmaceutical industry research and development, to the Canadian Parliament.

Drug patent holders, typically the manufacturers, submit to the board pricing information on all patented medicines. Along with the Canadian price, they must, when possible, submit price data from seven other nations. The board also considers the consumer price index and the prices of medicines in the same therapeutic class in Canada and in other countries. If necessary, the board also considers the manufacturing and marketing costs and other factors it considers relevant. Based on this information, the board decides if the price is excessive. If the board believes the price is excessive, it informs the manufacturer and requests a voluntary price reduction. If the manufacturer refuses to reduce the price, the board has the authority to hold public

hearings on the matter and can ultimately remove the drug's patent exclusivity. The price the patent holder submits is usually the "factory gate price" or the price at which the manufacturer sells the patented medicine to a wholesaler or directly to a hospital or pharmacy.

In addition to the board activity at the federal level, each Canadian province controls the price it reimburses pharmacies for drugs purchased by individuals receiving government drug benefits. In Ontario, the government provides free prescription drug benefits to all residents age 65 and older, to all persons receiving Family Benefits Assistance, General Welfare Assistance, Extended Health Care benefits, and to residents of Homes for Special Care.

Individuals who receive government drug benefits may fill their prescriptions at any retail pharmacy. The provincial government reimburses the pharmacy based on a formula of "best available price" plus 10 percent plus a professional fee, or the amount the pharmacy usually charges customers not receiving government drug benefits if the amount is lower. Ontario's government defines "best available price" as the lowest amount for which a listed drug product of a given dosage, form, and strength can be purchased in Canada for wholesale or retail sale in Ontario, less the value of any price reduction granted by the manufacturer or wholesaler or its representatives in the form of rebates, discounts, refunds, free goods, or any other benefits of a similar nature. The government adds a percentage to the best available price to account for the fact that every pharmacy may not be able to purchase drugs at that price.

The Ontario Ministry of Health issues a formulary developed with the advice of its Drug Quality and Therapeutics Committee. The purpose of the formulary is to assist in the provision of quality drug products at a reasonable cost. In considering drugs for inclusion on the formulary, the committee considers the proven medical value of the drug, potential harmful side effects, the availability of alternative drugs, and price. Higher priced drugs are included if they offer a therapeutic advantage. The formulary

designates certain drugs of the same chemical composition as interchangeable and provides a comparative pricing guide for them.

In addition to the formulary, the Ontario Ministry of Health produces a list of non-formulary benefits. Prescriptions for drugs on the non-formulary benefit list must be accompanied by a non-formulary benefit form.

Finally, for drugs that do not appear either in the formulary or on the non-formulary benefit list, the Ministry of Health may approve prescriptions on a case-by-case basis. Physicians requesting such approval must submit a request to the Ministry of Health, stating the clinical circumstances that necessitate the use of the unlisted drug.

Appendix B The Effect of Open Versus Restricted Formularies on Medicaid Expenditures

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Introduction

The concept of a formulary was originated by, and has been most thoroughly developed within, hospital settings. The American Society of Hospital Pharmacists (ASHP) defines a formulary as “a continually revised compilation of pharmaceuticals which reflects the current judgement of the medical staff (of a hospital).”¹ The ASHP goes on to describe that the “formulary system is a powerful tool for improving the quality and controlling the cost of drug therapy, and its use is strongly encouraged.”²

In the outpatient setting, formularies have been adapted to meet the needs of health maintenance organizations, private insurance plans, and state Medicaid programs. Formularies in outpatient settings, just as in hospitals, are usually created by, and maintained through, a pharmacy and therapeutics committee composed of physicians, pharmacists, and others. Not only does the list of drugs and dosage forms represent those drug products which the purchaser considers to be most useful or cost-effective, but in these outpatient settings it also becomes a means of defining the drug products which will be covered and reimbursed by the managed care or third party program. In other words, a drug formulary is not a singular concept and, consequently, formularies may be quite different across different settings.

Formularies are often labeled as either “open” or “restrictive” in nature. Basically an open formulary is an oxymoron in that “open” implies that all drug products are covered, while “formulary” implies a selected list of drug products. An open formulary, as the term is used, is no more than a compilation of all drug products which are available for use in the target patient

population. A “restricted formulary” is a ‘restricted’ list of drug products based on one or more of the following criteria. Drugs may be left off of a formulary because: (1) they are considered less than effective; (2) they are available over-the-counter; (3) they are used for cosmetic purposes and are not considered essential to the patient’s health; (4) they are subject to patient misuse and abuse (e.g., controlled substances); or (5) the program does not wish to cover them for administrative, cost, or other reasons.

Drug formularies may include drug products on their lists for a variety of reasons. Some formularies are lists of drug entities and dosage forms for which the products of a number of manufacturers are considered to be generically equivalent. Other formularies include drug products that are considered to be essential for proper patient care. Yet other drugs are listed on a formulary as being therapeutically equivalent or interchangeable for the same therapeutic purpose. One or more of the therapeutically equivalent drugs may be specified as the drug of choice or the first drug to be used within the therapeutic class before trying other therapies. Drug formulary systems which restrict the drugs that are covered and reimbursed almost always have a procedure by which the physician can get approval for a non-formulary drug that is medically necessary for a given patient. These provisions assure that even though access is restricted, it is not prohibited for patients who truly need a specific restricted therapy.

Impact of Formularies on Prescription Drug Costs

The Office of the Inspector General for the U.S. Department of Health and Human Services examined the Medicaid prescription drug costs per recipient for the the year 1988. The report Strategies to Reduce Medicaid Drug Expenditures³ states that:

“the five largest states which maintain restricted drug lists (California, New York, Ohio, Illinois, and Michigan) had Medicaid prescription drug costs per recipient of \$203.05 for 1988. The drug cost of the five largest states without restricted drug lists Pennsylvania, Texas, Florida, Massachusetts, and Indiana) was \$247.42 per recipient.

In addition, the report notes that eight of the 25 states with the highest total Medicaid drug payments annually averaged less than \$200 per recipient. Seven of these eight states maintained a restricted drug list. The report concludes that “the Medicaid prescription drug costs per recipient, in 1988, were 22 percent lower in the five largest states with restricted drug lists” when compared with the five largest states with open drug lists.

A comprehensive review of studies on the economic impact of Medicaid drug formularies covering the period 1972 to 1985 was published in the Journal of Pharmaceutical Marketing and Management.⁴ This article reviewed 11 studies known to have been published on various aspects of the economic impact of Medicaid formularies. Seven of these studies reported on the impact of a restrictive formulary on drug expenditures. Four studies^{5,6,7,8} found that restrictive formularies had not decreased drug expenditures, while three studies^{9,10,11} reported decreases in drug expenditures with restricted formularies. A 1988 study which examined the South Carolina Medicaid program found that upon opening up the drug formulary the average prescription expenditure per recipient increased.¹²

**Impact of
Formularies on
Total Program
Costs**

Even though three of the studies prior to 1985 and the 1988 South Carolina study found that restrictive formularies resulted in lower drug expenditures, all four of these studies reported an increase in total Medicaid program expenditures when a restrictive formulary was used. One additional study recently examined the economic impact of restricted formularies on total Medicaid expenditures by using a regression model on Medicaid expenditure data from 47 states.¹³ This study suggested, as had earlier studies, that there was no savings in total Medicaid expenditures from implementation of a restrictive formulary. One should note that all five of the studies reporting increased total Medicaid expenditures with restrictive formularies were sponsored by pharmaceutical companies or one of their trade associations.^{9,10,11,12,13} In contrast to these studies, one study from 1985 reported directly opposing evidence which “associated restricted formularies with lower overall Medicaid program costs.”⁸

All studies reporting on the relationship between type of formulary and total Medicaid expenditures acknowledged severe limitations in analyzing the relationship. First, the analyses reported represent measures of association and should not be construed as cause and effect relationships. Second, most of the studies admitted that there was an inability to account for other programmatic changes in the Medicaid program. In other words, other changes in Medicaid such as increased payment rates for hospitals or physicians may have occurred; expansion of services such as mental health, long term care, or other outpatient or inpatient services may have been implemented; and the eligibility criteria for certain target populations may have changed. Furthermore, it is not unusual for a Medicaid program to institute programmatic changes in one component of Medicaid, such as the drug program and then offset the savings expected from that component by expanding coverage of another component of the program such as outpatient mental health services or expanded patient eligibility criteria. If this trade off approach to program funding were used by a Medicaid program, it would not be surprising to find that a restrictive formulary is associated with higher total Medicaid expenditures. However, it would not be appropriate to conclude that the increase in program expenditures was due to the restrictive formulary. In fact, the savings from a restrictive drug formulary may have enabled an expansion of access through increased program benefits or expansion in the number of beneficiaries.

Conclusions

Based on a review of the literature regarding the use of formularies in Medicaid programs, two basic conclusions can be drawn. First, Medicaid programs with restricted formularies experience equal or lower drug costs per recipient when compared to Medicaid programs with open formularies. Second, total Medicaid program expenditures may increase or decrease with the implementation of a restrictive drug formulary. Drug formulary restrictions should be examined to determine which alternative health care products and services are likely to be used if a drug product restriction is adopted; and the cost of this alternative care should

be compared to the drug therapy cost to determine the impact that will result with respect to total Medicaid expenditures. Benefit and beneficiary changes in the broader Medicaid program must be accounted for before any increase in total Medicaid expenditures can be attributed to implementation of a restrictive drug formulary.

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Appendix C Discussion of Selected Aspects of the Medi-Cal Drug Benefit Program

One of the objectives of this study was to review the operation of selected aspects of the California Medical Assistance Program (Medi-Cal). More specifically, we attempted to address questions about the effect of the department's prior authorization process on prescribers' willingness to prescribe drugs not on Medi-Cal's list of contract drugs and the effect of the process on Medi-Cal beneficiaries' access to drugs, especially breakthrough drugs, not on the list of contract drugs. We also address the effect of federal reimbursement limits on the inclusion of certain drugs on the Medi-Cal list of contract drugs.

Effects of Prior Authorization on Beneficiaries and Prescribers

We collected evidence suggesting that Medi-Cal's prior authorization process may limit prescription drug treatment for Medi-Cal beneficiaries. We surveyed more than 400 physicians who treated Medi-Cal beneficiaries in fiscal year 1989-90 to determine whether prior authorization affects the selection of drugs, especially breakthrough drugs, prescribed to these beneficiaries. The physicians we surveyed were paid between \$1,001 and \$50,000 by Medi-Cal during the fiscal year. Approximately 64 percent of the physicians completed the survey.

The potential for Medi-Cal's prior authorization requirement to affect a beneficiary's access to breakthrough drugs appears minimal. Between 1988 and 1990, the Food and Drug Administration (FDA) approved the use of 15 new breakthrough drugs. We defined breakthrough drugs as drugs classified by the FDA as either a new molecular entity offering significant

therapeutic gain, known as "1A," or a high-priority AIDS drug, known as "1AA." As of July 1, 1991, 8 of 15 breakthrough drugs were on the list of contract drugs, so prior authorization would not be required for these drugs. According to the pharmaceutical program consultant for the department's drug discount program, the remaining 7 newly approved drugs are available to Medi-Cal beneficiaries through the department's prior authorization process. The department did not include these 7 drugs on the list of contract drugs because they either would be rarely or infrequently used by Medi-Cal beneficiaries, would not normally be prescribed to Medi-Cal beneficiaries who are not hospitalized, or the drug manufacturer did not petition the department to have them included on the list. In November 1990, the federal government enacted legislation that requires states to make new drugs approved by the FDA available six months after they are approved without prior authorization. Medi-Cal has adopted this requirement for drugs approved after the enactment of federal legislation. (See page 36 of this report for a description of how a drug manufacturer petitions the department to have a prescription drug included on the Medi-Cal list of contract drugs.)

Although we found the prior authorization process does not appear to limit a beneficiary's access to breakthrough drugs, our survey does indicate the process may inhibit physicians' willingness to prescribe certain drugs. More than 75 percent of the physicians who responded to the survey indicated that the prior authorization process at least sometimes prevents them from prescribing drugs not on the department's list of contract drugs. Some of these physicians said they experienced difficulty with the department's prior authorization process because of delays in getting through to the department for drug approval and said they also lacked information about what drugs are included on the list of contract drugs.

Two recent reports by the Office of the Auditor General discuss delays in receiving prior authorization for drugs prescribed to Medi-Cal beneficiaries. In the first two of four semi-annual reports to the Legislature (Report P-044 issued in January 1991

and Report P-117 issued in July 1991), we found selected providers experienced some delays in obtaining prior authorization for filling prescription drugs for Medi-Cal beneficiaries. In the January 1991 report, 6 of the 12 pharmacists we surveyed noted having had some difficulty getting through to the department to request prior authorization by telephone. Since that time, the department has attempted to expand its capability for receiving and processing requests for prior authorization by opening a new Medi-Cal drug unit in Stockton equipped with a new automated voice-response system.

Either the prescribing physician or the pharmacist filling the prescription may seek prior authorization on behalf of the Medi-Cal beneficiary, although, according to the chief of the department's field services branch, it is usually the pharmacist who seeks prior authorization. To mitigate some of the obstacles associated with prior authorization, the physicians in our survey said they take a variety of steps to ensure that Medi-Cal beneficiaries receive the prescribed drug when prior authorization is required. Physicians most frequently reported they make an extra effort to specify the medical necessity of the drug on the prescription to increase the likelihood the department will approve the drug. Also, 25 percent of these physicians or their staffs try to obtain prior authorization as soon as the drug is prescribed. Some physicians reported they seek prior authorization once the patient has been unsuccessful in getting the drug. Some physicians also refer Medi-Cal beneficiaries to particular community pharmacies that will try to obtain prior authorization. Instead of getting prior authorization for certain drugs, six physicians in the survey also give free samples of those drugs to Medi-Cal beneficiaries. In spite of these efforts, 69 percent of the survey respondents prescribed drugs not on the list of contract drugs, only to learn later that the beneficiaries never obtained them.

Similarly, the department's prior authorization process may limit Medi-Cal beneficiaries' access to certain drugs: 16 of the physicians who responded to our survey sometimes substitute the original, prescribed drug with an alternative one that does not require prior authorization. Some of the physicians stated that

in their opinion the substitute drug may or may not have the same therapeutic value as the one originally prescribed to the Medi-Cal beneficiary.

Effect of Federal Allowable Costs on Medi-Cal's List of Contract Drugs

One of the purposes of this study was to determine the effect of Federal Allowable Costs (FACs) on the inclusion of multiple-source drugs on the Medi-Cal list of contract drugs and the effect of FACs on the availability of those drugs to Medi-Cal beneficiaries.

According to the department's deputy director of medical care services, the cost of a drug is one of the five factors the department evaluates before adding a drug to the list of contract drugs. The other four factors are the drug's safety, effectiveness, essential need, and potential for misuse. The existence of a FAC for a drug the department is evaluating would be a point in favor of adding the drug to the department's list of contract drugs since the department is interested in controlling costs and a FAC is a cost control. If the department does add the drug, a FAC for the drug has certainly not hindered Medi-Cal beneficiaries' access to it.

Appendix D Pharmaceutical Manufacturers' Costs

We reviewed the 1990 annual reports for a sample of pharmaceutical manufacturers to determine their research, development, manufacturing, and marketing costs as a percent of sales.

Many pharmaceutical manufacturers are involved in manufacturing numerous products in addition to pharmaceuticals. For our review, we selected four companies whose pharmaceutical sales represented at least 70 percent of total sales in 1990. Total sales for these companies ranged from \$1.5 billion to \$7.7 billion. In addition to pharmaceuticals, products manufactured by the four companies include animal health products, agricultural chemicals, over-the-counter health products, and medical instruments and diagnostic products.

The four companies we reviewed spent an average of 24 percent of sales for materials and production, 35 percent for marketing and administration, and 14 percent for research and development. These figures, as shown in the following table, represent expenditures for the entire company, not just the pharmaceutical division.

Table D-1 Pharmaceutical Manufacturers' Expenditures as a Percent of Total Sales

Cost Category	Company 1	Company 2	Company 3	Company 4	Average
Materials and production	23.18%	24.12%	19.51%	29.34%	24.04%
Marketing and administration	31.13	42.70	36.92	27.47	34.56
Research and development	11.13	11.42	17.80	13.54	13.47

We were unable to determine separate cost components for the pharmaceutical divisions of these four companies. However, we identified three different companies that did report separate research and development costs for their pharmaceutical divisions. For these three companies, research and development amounted to an average of 17 percent of pharmaceutical sales. The Pharmaceutical Manufacturers Association reported an average cost for industry-wide research and development of 16 percent of pharmaceutical sales in 1988.

Appendix E Percent of Health Maintenance Organizations (HMOs) Using Various Techniques To Control Pharmaceutical Costs

Technique	Percent of HMOs Using Technique by Types of HMO ^a					All Types of HMOs ^b
	Group	IPA	Network	Staff		
Formulary	62%	28%	43%	75%	39%	
Over-the-counter drugs excluded from benefit coverage	94	92	74	61	86	
Required generic substitution	79	60	61	71	64	
Therapeutic substitution allowed	23	10	21	36	16	
Drug utilization review	62	52	51	62	54	
Contract bids for drug purchasing	78	86	91	87	84	

Source: The Marion Managed Care Digest HMO Pharmacy Edition 1990 and the SMG Marketing Group, Inc., based on a random stratified sample of HMOs throughout the United States.

^aTypes of HMO (as defined in the Marion Managed Care Digest HMO Edition 1990):

Group HMOs contract with one or a few larger multiple-specialty group practices to serve patients.

Independent Practice Association (IPA) HMOs use independent physicians practicing alone or in medical groups to care for enrollees.

Network HMOs contract for medical services from many individual physicians and group practices.

Staff HMOs use salaried staff physicians.

^bWeighted averages.

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August 22, 1991

Kurt R. Sjoberg
Auditor General (Acting)
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Dear Mr. Sjoberg:

Secretary Gould has asked me to respond to your August, 1991, draft report on "How Medi-Cal and Other Health Care Providers Manage Their Pharmaceutical Expenditures".

We believe the report contains a fair and reasonable assessment of how third parties, including Medi-Cal, control pharmaceutical expenses while maintaining access to needed drug products.

It is acknowledged that prescription drug expenditures in the Medi-Cal outpatient program have increased substantially in the last few years. We expect this trend to continue, since many new and important drug therapies are becoming available in the health care community. However, with continued use of our price and utilization controls as well as our ability to maximize savings through our state drug rebate program, we believe that we can improve access to these much needed medications and attain the greatest possible benefit to Medi-Cal beneficiaries while controlling unnecessary expenditures.

For your interest, we have enclosed a copy of a recent publication by T. Donald Rucker, Ph.D., regarding drug formularies.* To paraphrase from Dr. Rucker's quote from the Task Force on Prescription Drugs, while the use of a drug formulary is no guarantee of attainment of such ideals as high quality medical care, rational prescribing, effective utilization review, and control of costs, we find that the achievement of these objectives in a drug program is difficult if not impossible without its use.

Thank you for the opportunity to review the draft report. If you have any questions, please contact Mr. Michael Neff, Acting Chief Negotiator, Medical Drug Discount Program, at (916) 322-8963.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Wilson" with a small "J" and "B" above the main name.

Molly Joel Coyle, M.D., M.P.H.
Director

Enclosure

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*This publication is available from the Office of the Auditor General.

cc: **Members of the Legislature**
Office of the Governor
Office of the Lieutenant Governor
State Controller
Legislative Analyst
Assembly Office of Research
Senate Office of Research
Assembly Majority/Minority Consultants
Senate Majority/Minority Consultants
Capitol Press Corps